UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,793	08/25/2003	I-Horng Pan	PANI 3001 / EM	1239

23364 7590 12/02/2004

BACON & THOMAS, PLLC
625 SLATERS LANE
FOURTH FLOOR
ALEXANDRIA, VA 22314

EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,793	PAN ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-29 are pending in the application.

Election/Restrictions

The response to the election requirement with traverse in the response filed 9/13/04 is acknowledged. Applicant pointed out that all three of *A. capillaris, G. fructus* and *R. rhizoma* need to be present in the composition and therefore an election of species was not proper. However, in actuality, the Examiner was requiring the Applicant to elect a species of each of *A. capillaris*, *G. fructus* and *R. rhizoma*; i.e., a species of *A. capillaris* such as *Artemisiae Annuae* for example and so-on.

Nevertheless, the Examiner is hereby removing the requirement for election of species in order to facilitate prosecution in the case. A search was done on all of the species as found in claims 7, 8 and 9.

Claims 1-29 were examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 6-10, 16-17 and 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 states 'preparing the composition used for treatment'. This statement lacks antecedent basis in the claim. Correction is necessary.

Claims 1 and 16, part (d) further states 'separating said second solid phase and liquid phase'. This phrase is ambiguous in that it can mean that the solid phase and the liquid phase are separated from something other than each other. In order to clarify the claim, a suggestion to reword the claim follows: 'adding alcohol into said concentrate for precipitation and forming a second solid phase and a second liquid phase; separating said second solid phase from said second liquid phase and drying said second solid phase'. Note that the second instance of 'liquid phase' has been stated as 'second liquid phase' in order to be absolutely clear which liquid phase the phrase is refering to.

Claims 1, 2 and 16-17 recite 'alcohol solution'. It is unclear if this means an alcohol extract of the plants Rhei rhizoma and S. fructus or whether this means the plant mixed with alcohol. Clarification is necessary.

Claim 6 recites 'adding alcohol into said second liquid phase'. Is this refering to the second liquid phase after drying to form a third solid phase and a third liquid phase? The Examiner cannot be certain and therefore this phrase lacks clear antecedent basis.

Claims 7-9 and 22-24 recite 'and the herbs of the same genus'. It cannot be determined what the metes and bounds of this phrase are. What herbs are Applicant refering to? What does 'same genus' mean? Does Applicant intend to claim all genus of Artemisiae, Gardenia and Rheum? Clarification is needed.

Claim 10 states 'wherein step (a) further comprises boiling and stirring steps'. It is unclear if Applicant means that there is another boiling step (or steps) or if this was an inadvertent error since claim 1 already recites 'boiling'. Further, is 'stirring steps' refering to one stirring step, or multiple steps?

Claim 21 states 'adding alcohol into said second liquid phase....'. Again, it is unclear what phase this is refering to; is this after the separation and drying of the second liquid phase?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition and process which comprises species as indicated in claim 7-9, does not reasonably provide enablement for all genus of Artemisiae, Gardeniae and Rheum. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. It is noted that the reason claims 7-9 are rejected under this statute along with claims 1-6 and 10-29 is that claims 7-9 recite 'and herbs of the same genus' which may indicate that the claims include all other species of each genus which is not enabled.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of

experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

In the Instant case, Applicant is claiming a composition for treatment of liver disease, as well as methods for treatment thereof, with any genus of Artemisiae, Gardeniae and Rheum. However, the Instant specification has only taught an effective amount of plant genus as described specifically in claim 7-9; i.e. Rheum officinale for example. It is deemed that this lack of critical information would preclude the skilled artisan from making or using the claimed invention within the large breadth of the claimed scope for the following reasons:

It is well known in the herbal art that polarity of solvents plays a key role in determining the final product obtained by an extraction. However, because many phytochemicals remain undiscovered, the skilled artisan has to make his best educated guess as to what types of phytochemicals will be successfully extracted with a solvent of a particular polarity. Often times, unless the constituents in a particular plant extract have been well evaluated and documented in the literature, the skilled artisan must adhere to trial and error protocols in order to quantitatively determine phytochemical constituents present in samples obtained from respective extraction procedures. These

procedures are common when, for example, a plant or part thereof has been documented in the literature as possessing some medicinal quality. The skilled artisan will carry out numerous tedious extraction protocols in attempt to isolate the particular ingredient(s) which has/have this medicinal quality. Typically, beginning with the first crude extraction, ***it is a guess*** as to weather or not the extract will possess the inherent medicinal quality. Take for example, the grape, *Vitis vinefera*. If this fruit was documented in the literature as having a particular medicinal quality, the skilled artisan may feel the need to extract and isolate the medicinally beneficial ingredient(s)therefrom.

The skilled artisan will, by trial and error, attempt to perform step-wise extractions to uncover the active extract. If the first extraction attempt with a particular solvent fails, another solvent will be tried. Thus, beginning with the initial extraction, a first product is yielded which was extracted with the solvent, and a second product is yielded which remains because it did not possess a similar polarity to the solvent. Each successive extraction yields different products due to the exclusion of ingredients based on the polarity of the solvents solvating constituents with similar polarities. Subsequently, *the properties of each respective product (extract) would need to be evaluated for efficacy*.

Hence, ***each product obtained from a plant extraction is unpredictable in nature***. Even the most skilled of artisans would need to quantify each product for

constituents as well as medicinal efficacy. Applicants have not provided any information with regard to how to make or use any 'extract' from any genus of Artemisiae, Gardeniae and Rheum. The specific species of these genuses as taught in the Instant specification are not considered a representative number of each genus. Thus, to practice the instant invention in a manner *consistent with the breadth of the claims* would not require just a repetition of the work that is described in the instant application but a **substantial inventive contribution on the part of a practitioner** to ascertain what other extract (s) will actually perform the intended function as recited in the claims. This inventive contribution would involve tedious trial and error protocols without the expectation of success for the reasons set forth *supra.*

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that:

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

11/19/04